

REMARKS

This is in response to the Office Action mailed 3/6/09.

Claims 1-14, 16, and 18-33 are pending. Claims 3-14 have been withdrawn from consideration.

Claim 18 has been amended to change “an IRM conjugated directly to a lipid group” to “an IRM conjugated to a lipid” as suggested by the Examiner.

35 USC § 112 Rejections

Claim 18 was rejected under 35 USC § 112, first paragraph. Claim 18 has been amended as noted above, as suggested by the Examiner.

35 USC § 103(a) Rejections

Claims 1-2, 16, and 18-33 were rejected as allegedly being obvious over Krieg et al. (US 2003/0139364) in view of Ulrich (US 6,486,214). Applicants respectfully disagree.

Applicants acknowledge that Krieg et al. disclose the uses of imidazoquinolines, including resiquimod, for cancer treatment and discuss a variety of means of delayed release delivery (paragraph 335). However, Krieg et al. only disclose the administration of imidazolquinoline agents by “any ordinary route for administering medications” (paragraph 378). Krieg et al. do not disclose or suggest administration of imidazolquinoline agents via placement *within* the cancer tissue. Rather, Krieg et al.’s disclose a variety of routes and locations for administering imidazolquinoline agents to different anatomical areas but do not suggest release of the agent from within a tumor (paragraph 379). In contrast, the local administration of a depot preparation of resiquimod directly within the localized cancer tissue is

a key aspect of the claimed invention. Krieg et al. do not disclose or suggest introducing resiquimod intra-tumorally.

Krieg et al. teach the administration of cancer vaccines to antigen presenting cells (paragraph 305). Antigen presenting cells are immune cells such as B cells, macrophages, and dendritic cells which, upon activation in the presence of cancer antigens, process and present those antigens to other immune cells. (Trombetta, ES and I Mellman. 2005. Cell Biology of Antigen Processing In Vitro and In Vivo. *Annu. Rev. Immunol.* 23:975-2028.) Antigen presenting cells, unlike the cancer cells, are found throughout the body. (Lanzavecchia, A and F. Sallusto. 2000. Dynamics of T Lymphocyte Responses: Intermediates, Effectors and Memory Cells. *Science* 290:92-97.)

Krieg et al.'s vaccination strategy does not disclose or suggest the activation of antigen presenting cells in the vicinity of cancer cells because the vaccine itself (not the cancer cells) provides the antigen. Because antigen presenting cells are located throughout the body, a cancer vaccine may be administered at a location distant to the tumor. In fact, at the time of the claimed invention, the tumor microenvironment was known to be hostile to immune responses (Jain, RK. 1998. Delivery of molecular and cellular medicine to solid tumors. *J. of Control. Release* 53:49-67.) Thus, it would not have been obvious to administer the IRM depot preparation, meant to stimulate the immune system, *within* the localized tumor region.

Furthermore, a cancer vaccine, as defined by Krieg et al., does not contain imidazoquinoline (paragraph 306). Krieg et al. suggests that the imidazoquinoline administered in conjunction with the vaccine should be administered systemically, not locally (paragraph 29). There is no disclosure or suggestion by Krieg that the local administration of resiquimod is

important; whereas local administration is an important limitation of the invention, as explained at page 2, lines 8-20, of the specification.

Ulrich (US 6,486,214) also teaches the administration of drugs using extended release implants but fails to suggest that the implant be placed within the cancer tissue. Like Krieg et al., Ulrich fails to teach that resiquimod or any other drug should be administered within the localized cancer tissue. There is nothing to suggest that either Krieg et al. or Ulrich contemplated the placement of a depot formulation *within* the cancer tissue, an important limitation of the claimed invention.

Applicants respectfully request withdrawal of the rejection.

In view of the above, it is submitted that the application is in condition for allowance. Examination and reconsideration of the application as amended are requested.

Applicant requests a telephone interview to more fully understand the Examiner's position and advance this case to issuance.

Respectfully submitted,

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